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10/814,002	03/30/2004	Balram Ghosh	206,487	6062

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EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,002	GHOSH ET AL.	
	Examiner	Art Unit	
	Stephanie K. Mummert, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,29 and 77-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 29, 77-85* is/are rejected.

7)☒ Claim(s) *1,4-12,16-19,29 and 80-85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1-19, 29 and 77-85 in the reply filed on November 6, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-28, 30-76 and 86-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 6, 2006.

Claims 1-19, 29 and 77-85 are pending and will be examined.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 29 and 77-85 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to "novel gene variants" and "pharmacogenetic markers", both of which represent products that are not distinguishable from the specific sequences that are present in nature. Therefore, because there is nothing that distinguishes these markers as isolated or distinct from products of nature, the claims are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 1-19 and 29, the inclusion of the term "novel" in the preamble to the claim, stated specifically as "novel gene variant" is vague and indefinite. It is unclear what structural or functional limitation the term novel is intended to impart on the gene variant claimed. Furthermore, the inclusion of the term "novel" is inappropriate because it represents legal phraseology.

6. Regarding claims 10-12 and 15, the inclusion of multiple haplotypes within each claim indicates separate and distinct sequences that do not comprise the same sequence as disclosed in SEQ ID NO:1 or 2. It is unclear what specific nucleic acid sequence or sequences are being claimed in each of these claims?

7. Regarding claims 16-19, it is unclear from the claim how the "percentage frequency of the R1 locus dinucleotide" (claims 16-17) or the "percentage frequency of the R3 locus dinucleotide" (claims 18-19) imposes a structural limitation on the nucleic acid product represented by these claims?

Claim Objections

8. Claims 10-12 and 29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

9. Claim 1 is objected to because of the following informalities: at the end of step (a), after the term "and" a period is included. As the claim continues to step (b), the period should be replaced with a semicolon. Appropriate correction is required.

10. Claim 4 is objected to because of the following informalities: there appears to be a typographical error. As currently written, the claims recite "disorders are selected are from group", wherein there is an apparent extra "are" between "selected" and "from". Appropriate correction is required.

11. Claims 6, 7, 80, 82, 83 are objected to because of the following informalities: In each of these claims, there appears to be a typographical error. As currently written, the claims recite "said variants are useful are predicting", which leaves an extra "are" between "useful" and "predicting". Appropriate correction is required.

12. Claim 17 is objected to because of the following informalities: in this claim, the specific allele does not have a number associated with the term "allele". Instead, the allele is just referred to generically as "allele". Appropriate correction is required.

13. Claims 4-9, 16-19, 29, 80-85 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As currently written, these claims do not place any structural limitation on the nucleic acid that comprises the gene variant or pharmacogenetic marker claimed in the independent claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-9, 17-19 and 77-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. (Genomics, 1998, vol. 52, p. 192-200). Patel teaches the mapping and characterization of the human STAT6 gene (Abstract).

With regard to claim 1 and 77, Patel teaches gene variants or pharmacogenetic markers having of SEQ ID Nos. 1 and 2 of Signal Transducer and Activator of Transcription-6 (STAT-6)

gene useful in predicting susceptibility of a subject to atopic disorders, said gene variants having following characteristics:

(a) The SEQ ID No. 1 has 1-392 contiguous nucleotides containing one or more group of GT dinucleotide polymorphisms at positions from 125 to 168 of R1 locus (see attached sequence alignment, HSSTATSIX1, specifically nucleotides 908-1299, which comprises SEQ ID NO:1 and the repeat region, located at nucleotides 1032-1074), and;

(b) the SEQ ID No.2 has 1 to 336 contiguous nucleotides containing one or more group of GT dinucleotide p olymorphisms at positions from 87 to 116 bases of R3 locus (see attached sequence alignment, HSSTATSIX1, specifically nucleotides 3605-3940, which comprises SEQ ID NO:2 and the repeat region, located at nucleotides 3691-3720).

With regard to claim 2 and 78, Patel teaches an embodiment of claim 1, wherein SEQ ID No.1 is associated with R1 locus (see attached sequence alignment, HSSTATSIX1, specifically nucleotides 908-1299, which comprises SEQ ID NO:1 and the repeat region, located at nucleotides 1032-1074) and SEQ ID No.2 is associated with R3 locus of STAT-6 gene (see attached sequence alignment, HSSTATSIX1, specifically nucleotides 3605-3940, which comprises SEQ ID NO:2 and the repeat region, located at nucleotides 3691-3720).

With regard to claim 3 and 79, Patel teaches an embodiment of claim 1, wherein a subject is human (see attached sequence alignment(s), where it is noted the sequence source is human).

Regarding claims 4-9 and 80-85, the limitation regarding which disease that is associated with the specific gene variant does not impose a structural limitation on the sequence or structure of the nucleic acid. Therefore, these claims are rejected in view of the nucleic acid sequence, represented by AH006951 described above with regard to claims 1 and 2.

Regarding claims 17-19, the limitation directed to the percentage frequency of the specific R1 or R3 alleles does not place a structural limitation on the nucleic acid claimed. Therefore, these claims are considered rejected in view of the rejections stated previously above because the sequence of the R3 locus, or SEQ ID NO:2, depicts 15 repeats, meeting the limitation of claims 17-19.

16. Claims 1-9, 13-19 and 77-85 are rejected under 35 U.S.C. 102(a) as being anticipated by Nagarkatti et al. (Journal of Human Genetics, 2002, vol. 47, p. 684-687). Nagarkatti teaches the identification of three polymorphic (CA) repeat regions and the examination of allelic frequency and haplotypes was conducted (Abstract).

With regard to claim 1 and 77, Nakargatti teaches gene variants or pharmacogenetic markers having of SEQ ID Nos. 1 and 2 of Signal Transducer and Activator of Transcription-6 (STAT-6) gene useful in predicting susceptibility of a subject to atopic disorders, said gene variants having following characteristics:

(a) The SEQ ID No. 1 has 1-392 contiguous nucleotides containing one or more group of GT dinucleotide polymorphisms at positions from 125 to 168 of R1 locus (see attached sequence alignment, HSSTATSIX1, which matches accession number AH006951 referenced p. 685, col. 1, specifically nucleotides 908-1299, which comprises SEQ ID NO:1 and the repeat region, located at nucleotides 1032-1074; also see Table 1, 'STAT6 gene' heading), and;

(b) the SEQ ID No.2 has 1 to 336 contiguous nucleotides containing one or more group of GT dinucleotide p olymorphisms at positions from 87 to 116 bases of R3 locus (see attached sequence alignment, HSSTATSIX1, which matches accession number AH006951, specifically

nucleotides 3605-3940, which comprises SEQ ID NO:2 and the repeat region, located at nucleotides 3691-3720; also see Table 1, 'STAT6 gene' heading).

With regard to claim 2 and 78, Nagarkatti teaches an embodiment of claim 1, wherein SEQ ID No.1 is associated with R1 locus (see attached sequence alignment, HSSTATSIX1, which matches accession number AH006951 referenced p. 685, col. 1, specifically nucleotides 908-1299, which comprises SEQ ID NO:1 and the repeat region, located at nucleotides 1032-1074; and see Table 1, 'STAT6 gene' heading, where a CA/GT repeat in the R1 locus is described;) and SEQ ID No.2 is associated with R3 locus of STAT-6 gene (see attached sequence alignment, HSSTATSIX1, which matches accession number AH006951, specifically nucleotides 3605-3940, which comprises SEQ ID NO:2 and the repeat region, located at nucleotides 3691-3720; Table 1, 'STAT6 gene' heading, where a CA/GT repeat in the R3 locus is described;).

With regard to claim 3 and 79, Nagarkatti teaches an embodiment of claim 1, wherein a subject is human (see p. 684-5, 'subjects and methods' where the individuals analyzed are described in detail; also see accession number AH006951, where it is noted the sequence source is human).

Regarding claims 4-9 and 80-85, the limitation regarding which disease that is associated with the specific gene variant does not impose a structural limitation on the sequence or structure of the nucleic acid. Therefore, these claims are rejected in view of the nucleic acid sequence, represented by AH006951 described above with regard to claims 1 and 2.

Regarding claims 13-15, while the inclusion of specific haplotypes imposes a structural limit on the number of CA repeats present in the sequence comprising SEQ ID NO:1 and 2, the

limitations regarding specific p values does not impose a structural limitation on the nucleic acid sequence. Therefore, the claims are rejected solely on the basis of specific haplotypes disclosed by Nagarkatti.

With regard to claim 13, Nagarkatti teaches an embodiment of claim 1, wherein CA nucleotide repeat is on 17 allele of R1 locus and on 15 allele of R3 locus of the STAT-6 gene (Table 2, where haplotypes comprising 17_15 were identified in the STAT-6 gene).

With regard to claim 14, Nagarkatti teaches an embodiment of claim 1, wherein CA nucleotide repeat is on 16 allele of R1 locus and on 15 allele of R3 locus of the STAT-6 gene (Table 2, where haplotypes comprising 16_15 were identified in the STAT-6 gene).

With regard to claim 15, Nakargatti teaches an embodiment of claim 1, wherein haplotypes 17_14, 23_16 and 24_16 of the STAT-6 gene (Table 2, where haplotypes 24_16 were identified in the STAT-6 gene; see also p. 686, col. 1, where it is noted that Table 2 represents 76% of all haplotypes and others were not included).

Regarding claims 16-19, the limitation directed to the percentage frequency of the specific R1 or R3 alleles does not place a structural limitation on the nucleic acid claimed. Therefore, these claims are considered rejected in view of the rejections stated previously above.

Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nyce et al. (WO0062736; October 2000) discloses oligonucleotide compositions for prophylactic, preventive and therapeutic treatments associated with impaired respiration, lung

allergies and/or inflammation and discloses sequences of STAT6 (Abstract and attached alignments).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert, Ph.D. whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JEFFREY FREDMAN
PRIMARY EXAMINER
2/2/02

Stephanie K. Mummert

Stephanie K Mummert, Ph.D.
Examiner
Art Unit 1637

SKM